

We are ready to sock it to ‘em! The ‘STOPCUTS’ pilot study.

It is possible to do a full trial of protective socks for skin tears.

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What’s the problem?

- For the over-70s, the skin on the arms and legs becomes thinner and more fragile.
- Skin can also get thin when certain medical conditions need courses of treatment with oral steroids and/or ‘blood thinning’ drugs such as warfarin. Diabetics are also at risk.
- Fragile skin is easily injured and can tear, even after a minor knock or scrape against common household or garden items.
- Skin tear injuries are common and can be very painful and confidence-sapping.
- They are prone to infection, take a long time to heal and are expensive for the NHS to treat.



Two skin tears (lacerations) on the shin of an 80-year-old woman, sustained after she fell down the stairs. The skin edges no longer quite meet.

What have we done about it?

We wanted to know if it would be possible to do a full randomised controlled trial of ‘Dermatuff’ protective socks to prevent skin tears **by doing a pilot study first**. We hoped to do the pilot study in care homes as this is also an under-researched area. The use of smart phones for randomisation and data entry was also a novelty.

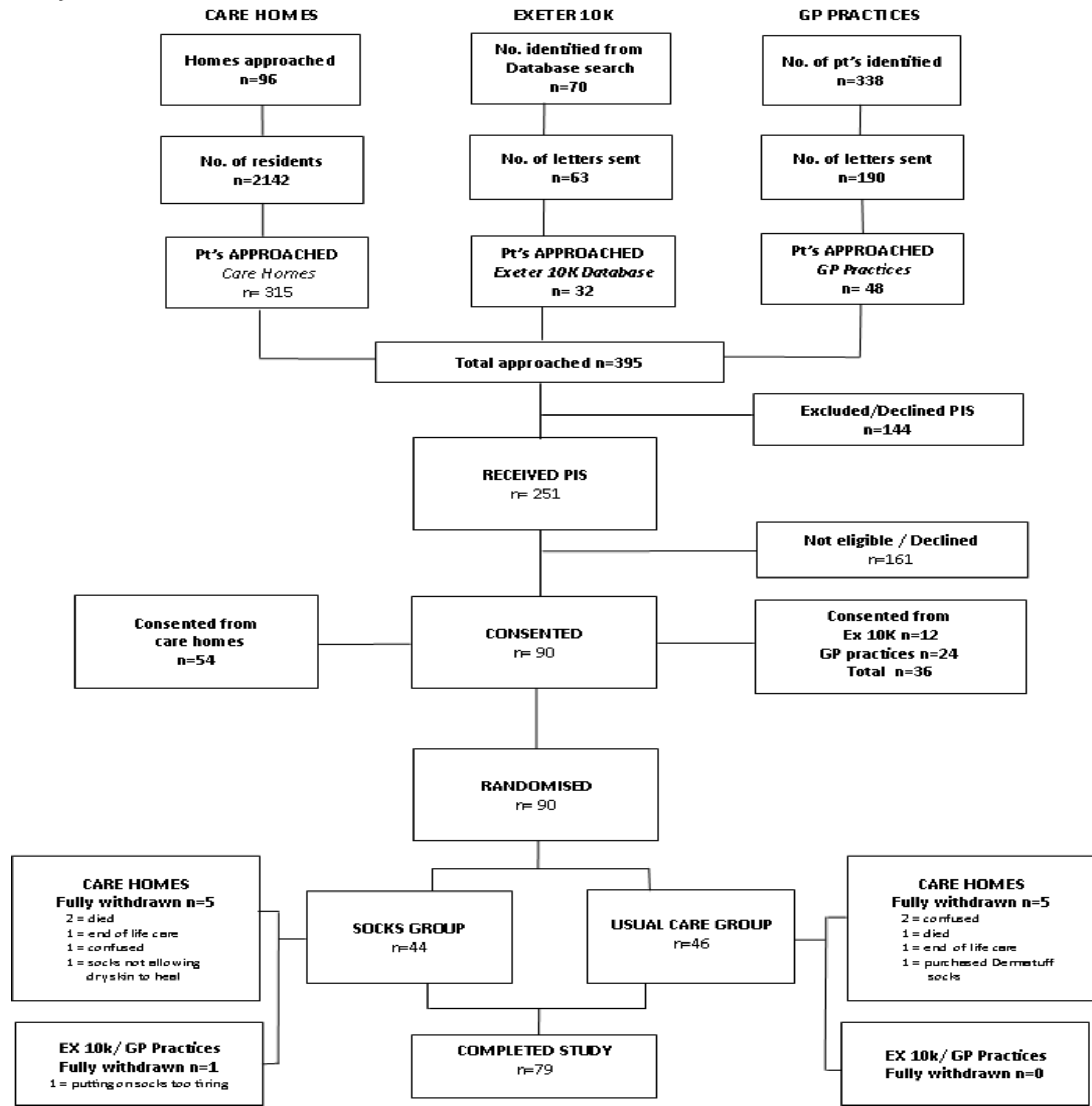
- Protective knee-length ‘Dermatuff’ socks/ stockings are designed to prevent skin tears to the lower leg.
- They are woven with cut-resistant Kevlar fibres - used in stab-proof vests and light-weight body armour - with an inner Terry cushioning layer to absorb knocks and bumps. The foot section is cotton.



We had to approach a lot of care home residents to get the 90 we needed for the pilot study (figure 1). Many of the care home residents could not give consent because of dementia, so only 54 of them were recruited and the rest came from GP practices and people in the community who have thin skin – found in a research volunteers database (‘Exeter 10K’). In this diagram, a PIS is a participant information sheet about the study.

STOPCUTS CONSORT DIAGRAM, Draft v0.6 31/07/15

Figure 1

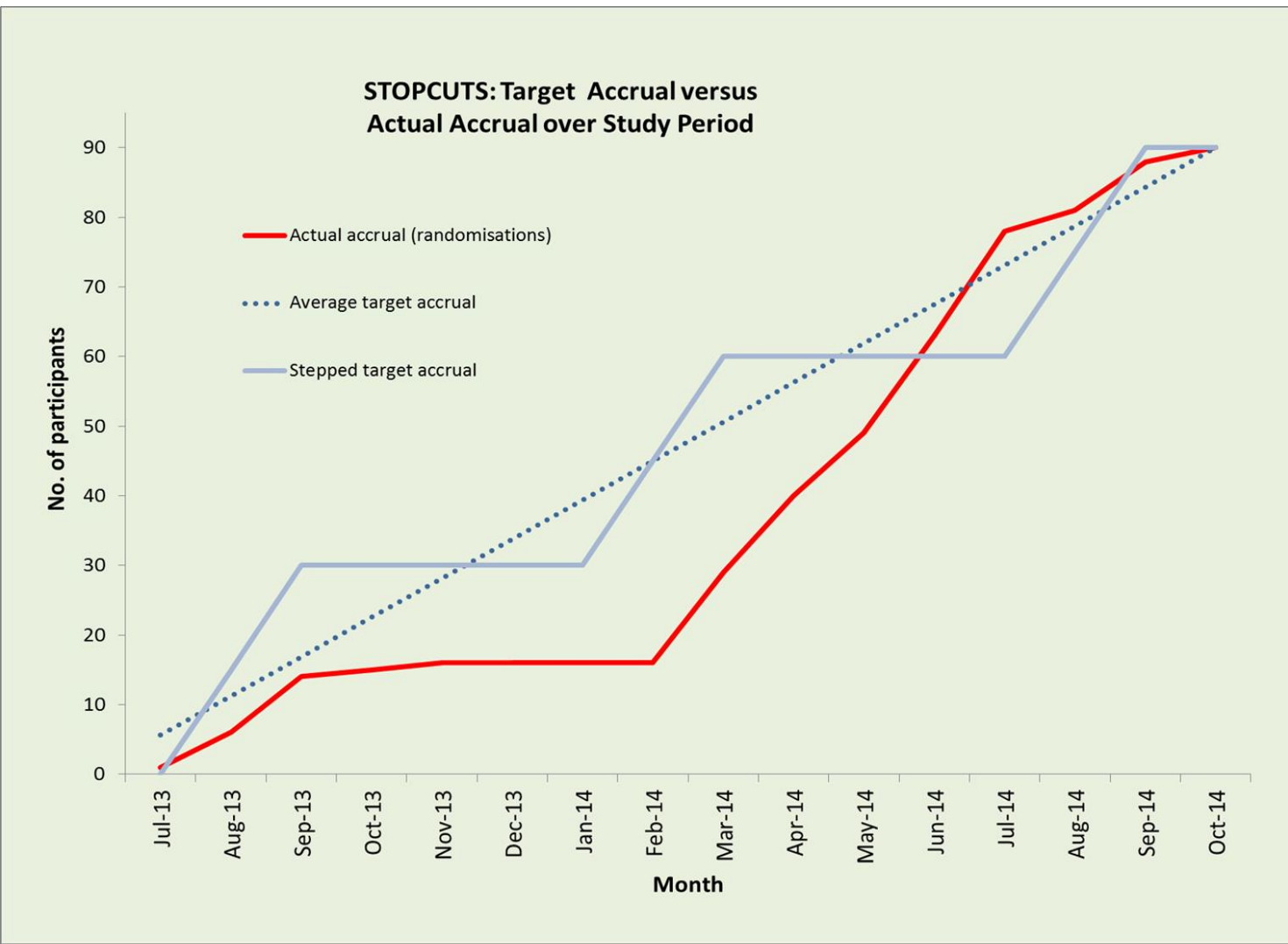


Methods

- Participants were randomised to either wear ‘Dermatuff’ protective socks on a daily basis or their usual clothing for 16 weeks (=112 days).
- Working closely with care home staff, research nurses photographed, measured and classified the severity of all skin tear injuries. These were followed up until healed.
- Participants in both groups completed quality of life questionnaires at baseline, 16 weeks and in the event of a skin tear injury.
- Experiences of using the socks and/or taking part in the pilot trial were captured through semi-structured interviews and daily diaries.
- Focus groups were held for care home managers and health professionals involved in the study.

Results

Figure 2



- We achieved full recruitment and follow-up of 90 participants within the allotted time and budget. (July 2013 to Jan 2015) (figure 2). Recruiting from GP practices and the community from Feb 2014 helped us to catch up!
- Median age of participants was 85 years.
- Of the 44 participants in the socks group, 27(61.4%) wore the socks for the full 112 days. 11 (25%) discontinued them after a while and another 6 withdrew mostly due to poor health or lost capacity.
- In the control group 41/46 (89.1%) completed the trial and 5 withdrew.
- There were 12 adverse events which had a causal relationship to the socks: 8 were mild (mostly lower leg discomfort) and 4 were moderate (e.g. blisters, itching, pain in shoulder from putting them on). All recovered.
- There were 10 Serious Adverse Events (SAE’s) but these were either unlikely to be related or were not related to the protective socks.
- 79/90 (88%) of the expected 16-week questionnaires and 482/704 (68.5%) of the weekly diaries were received. 680 comments were recorded in total.
- 31 skin tear injuries occurred in 18 (20%) of the 90 participants over a period of 112 days. Further results are pending publication.

Conclusions

We have shown that it is possible to conduct a trial of the effectiveness of Dermatuff socks to prevent lower leg skin tears among older people and those at risk – whether living in care homes or in the community.

Reference

Powell RJ, Hayward CJ, Snelgrove CL, Polverino K, Park L, Chauhan R, Evans PH, Byford R, Charman C, Foy CJW and Kingsley A. (2015) Pilot randomised controlled trial of protective socks against usual care to reduce skin tears in high risk people “STOPCUTS”: study protocol. *Pilot and Feasibility Studies*. <http://www.pilotfeasibilitystudies.com/content/1/1/12#B29>

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